PCT WORLDD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PPUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 : A61B 17/32	A1	(11) International Publication Number: **WO 00/51508** (43) International Publication Date: 8 September 2000 (08.09.00)

(21) International Application Number: PCT/US00/05505

(22) International Filing Date: 2 Marcbh 2000 (02.03.00)

(30) Priority Data:
09/260,297 2 March 1999 (02.003.99) US

(71) Applicant: SOUND SURGICAL TECHNNOLOGIES, LLC [US/US]; 1300 Plaza Court North, #2093, Lafayette, CO 80026 (US).

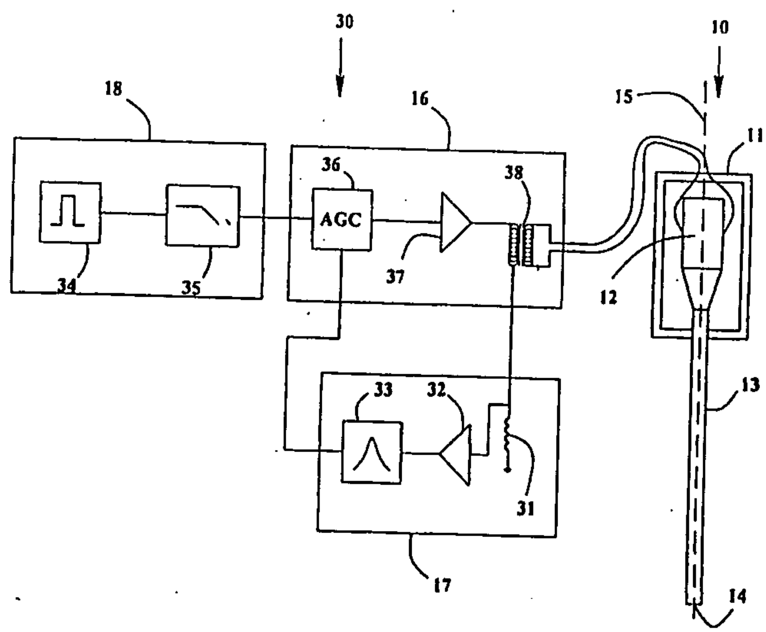
(72) Inventor: CIMINO, William, W.; 578 West t Sagebrush Court, Louisville, CO 80027 (US).

(74) Agent: YOUNG, Thomas, H.; Dorsey & WPhitney LLP, Suite 4400, 370 17th Street, Denver, CO 802022-5644 (US).

(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: PULSED ULTRASONIC DEVICE ALND METHOD

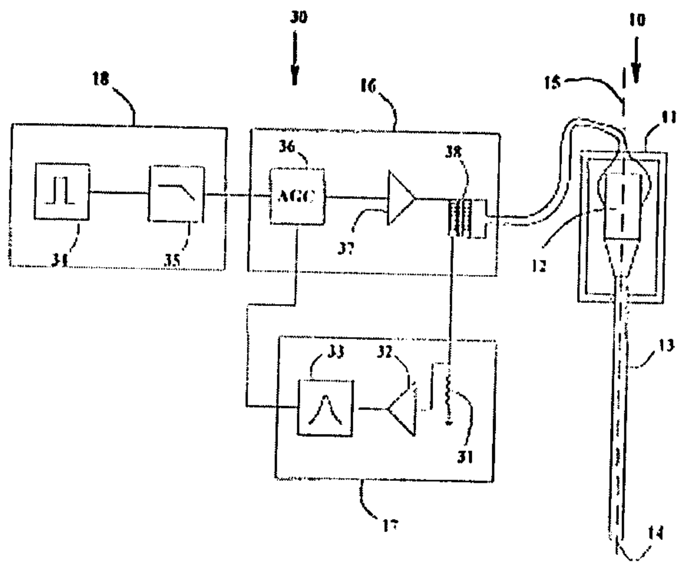


(57) Abstract

This invention relates generally to an ultrassonic surgical apparatus (10). More particularly, this invention relates to an improved method, and apparatus for generating profiled pulsees of ultrasonic frequency vibratory energy at a distal surface of an ultrasonic applicator (13) of an ultrasonic surgical instrument for applicaation to tissues of a patient with specific relationships between a magnitude of the pulse of ultrasonic frequency vibratory energy, and a duratidon of the pulse of ultrasonic frequency vibratory energy so that the ultrasonic applicator (13) can be driven to vibratory amplitudes previoussly not achievable, and a more expedient surgical effect obtained.

MicroPatent® PatSearch FullText: Record 10 of 132

Search scope: US EP WO JP; Full patent spec.
Years: 2000-2001
Text: "Ultrasonic" and "Band pass filter"



Download This Patent Family Lookup

Go to first matching text

WO0051508
PULSED ULTRASONIC (^) DEVICE AND METHOD
SOUND SURGICAL TECHNOLOGIES, LLC
Inventor(s): CIMINO, William, W.
Application No. US0005505, **Filed** 20000302, **A1 Published** 20000908

Abstract: This invention relates generally to an ultrasonic (^) surgical apparatus (10). More particularly, this invention relates to an improved method, and apparatus for generating profiled pulses of ultrasonic (^) frequency vibratory energy at a distal surface of an ultrasonic (^) applicator (13) of an ultrasonic (^) surgical instrument for application to tissues of a patient with specific relationships between a magnitude of the pulse of ultrasonic (^) frequency vibratory energy, and a duration of the pulse of ultrasonic (^) frequency vibratory energy so that the ultrasonic (^) applicator (13) can be driven to vibratory amplitudes previously not achievable, and a more expedient surgical effect obtained.

Int'l Class: A61B01732;

Priority: US 09/260297 19990302

Designated States: AL AM AT AU AZ BA BB BG BR BY CA CH CN CU CZ DE DK EE ES FI GB GD GE GH GM HR HU ID IL IN IS JP KE KG KP KR KZ LC LK LR LS LT LU LV MD MG MK MN MW

MX NO NZ PL PT RO RU SD SE SG SI SK SL TJ TM TR TT UA UG UZ VN YU ZW GH GM KE LS MW SD SL SZ TZ UG ZW AM AZ BY KG KZ MD RU TJ TM AT BE CH CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN GW ML MR NE SN TD TG

Go to Claims

Detailed Description

PULSED **ULTRASONIC (^)** DEVICE AND METHOD

SPECIFICATION

CROSS-REFERENCE TO RELATED APPLICATION

This application claims the benefit of priority of U.S. Patent Application No. 09/260,297, filed March 2, 1999.

BACKGROUND OF THE INVENTION

This invention relates generally to **ultrasonic (^)** surgical apparatus. More particularly, this invention relates to an improved method and apparatus for generating profiled pulses of **ultrasonic (^)** frequency vibratory energy at a distal surface of an **ultrasonic (^)** applicator of an **ultrasonic (^)** surgical instrument for application to tissues of a patient with specific relationships between a magnitude of the pulse of **ultrasonic (^)** frequency vibratory energy and a duration of the pulse of **ultrasonic (^)** frequency vibratory energy so that the **ultrasonic (^)** applicator can be driven to vibratory amplitudes previously not achievable and a more expedient surgical effect obtained.

Ultrasonic (^) surgical devices typically operate at frequencies between 20 kHz and 60 kHz and have application in many surgical specialties including neurosurgery, general surgery, and ophthalmic surgery. In general it is known that **ultrasonic (^)** surgical devices generate **ultrasonic (^)** frequency vibratory energy that is applied to an **ultrasonic (^)** applicator that vibrates longitudinally and which contacts the tissues of a patient. The **ultrasonic (^)** surgical device may, among other surgical effects, cut, fragment, and/or coagulate the contacted tissues of the patient.

Ultrasonic (^) surgical devices are constrained in their ability to generate **ultrasonic (^)** frequency vibratory energy due to limits imposed by machining tolerances and by limits inherent in the physical characteristics of the materials used to fabricate the devices. For example, titanium alloys are often used for fabrication of the **ultrasonic (^)** applicator that is used to contact the tissues of a patient.

Titanium alloys have inherent fatigue strength and stress limitations that cannot be exceeded or the **ultrasonic (^)** applicator will crack. As a further example, the **ultrasonic (^)** motor that converts supplied electrical power to **ultrasonic (^)** frequency vibratory energy may be fabricated from piezoelectric ceramics. Piezoelectric ceramics have inherent limitations on their ability to efficiently convert electrical energy to vibratory energy, including limits on applied voltage so that the ceramic elements do not loose their piezoelectric properties.

However, a phenomenon referred to in this disclosure as 'mode coupling', is most often responsible for establishing the upper perforinance bound of an **ultrasonic (^)** surgical device. Mode coupling occurs when the vibratory amplitude of an **ultrasonic (^)** applicator of an **ultrasonic (^)** surgical device is

increased to such a level that the **ultrasonic (^)** frequency vibratory energy at the desired resonant frequency is coupled to other modes of vibration, referred to herein as 'parasitic modes'.

The parasitic modes of vibration may be at lower frequencies, near-by frequencies, or higher frequencies, depending of the design of the system. The parasitic modes of vibration may be longitudinal modes or they may be transverse modes, or they may be more complicated coupled modes. Mode coupling is especially troublesome when the **ultrasonic (^)** applicator is an elongate probe or catheter with a length greater than one wavelength at the resonant frequency of the particular **ultrasonic (^)** surgical device. Mode coupling may occur for **ultrasonic (^)** applicators shorter than one wavelength and may also occur for **ultrasonic (^)** applicators that are not shaped like an elongate probe, for example, flat or convex radiating surfaces.

The most common type of mode coupling encountered for **ultrasonic (^)** surgical devices is the stimulation of a lower or near-by frequency transverse mode so that the **ultrasonic (^)** applicator vibrates in the desired longitudinal vibratory mode and an undesired transverse vibratory mode simultaneously. This type of coupled vibration can easily cause stresses in the **ultrasonic (^)** applicator material sufficient to break the **ultrasonic (^)** applicator.

Ultrasonic (^) surgical devices that operate at high vibratory amplitudes also generate undesirable heat, primarily in the **ultrasonic (^)** motor, but also in the material of the **ultrasonic (^)** applicator due to internal friction and other losses as the **ultrasonic (^)** applicator vibrates. If the **ultrasonic (^)** motor becomes too hot during a typical procedure then active cooling, such as forced air or water cooling, of the **ultrasonic (^)** motor is required, making the **ultrasonic (^)** surgical handpiece more expensive and more cumbersome due to the additional supply lines. If the **ultrasonic (^)** applicator becomes hot then the tissues of a patient may be unnecessarily burned.

Mode coupling and heat generation have placed fundamental limits on the performance of **ultrasonic (^)** surgical systems. What has been discovered, and is disclosed herein, is an **ultrasonic (^)** surgical apparatus and method for generating profiled pulses of **ultrasonic (^)** frequency vibratory energy such that mode coupling is suppressed or eliminated so that the **ultrasonic (^)** applicator can be driven to desired vibratory amplitudes which were previously unobtainable, thus increasing the expediency of a surgical procedure. Further, because the expediency of the surgical procedure is increased, the effective dose of **ultrasonic (^)** frequency vibratory energy delivered to the tissues of a patient is minimized. Still further, because the **ultrasonic (^)** applicator is driven to high vibratory amplitudes for only short periods of time, internal heating of the **ultrasonic (^)** applicator is reduced, as is the electrical power consumed by the **ultrasonic (^)** motor.

The use of switchable or pulsed vibratable tools is disclosed in patents. United States Patent Number 4,614,178 to Harlt has a dose meter and a control circuit for switching the mode of operation in an **ultrasonic (^)** therapeutic apparatus. A detector circuit is used to monitor the output to a treatment head so that a time measurement of the duration of the treatment can be switched between an enabled or disabled state. This therapeutic, not surgical, device is intended to deliver heat to the tissues of a patient and the switch between states of operation is used to ensure that a proper dose of heat is delivered to the patient, United States Patent Number 3,980,906 to Kuris has a driving circuit for producing bursts of **ultrasonic (^)** frequency oscillations between 10 kHz and 1,000 kHz at repeated sonic intervals in the range of 10 Hz to 1,000 Hz, the repeated sonic intervals of **ultrasonic (^)** frequency oscillation applied to **ultrasonic (^)** instruments such as toothbrushes and razors. This patent uses bursts of **ultrasonic (^)** energy to reduce sliding friction for smoother motion when shaving and to provide a satisfactory tactile sense of operation to a user. Each burst of **ultrasonic (^)** mechanical vibration lasts fo r Y2of the sonic interval, resulting in on-off intervals of equal duration.

United States Patent Number 4,343,111 to Inoue has an **ultrasonic (^)** machining method wherein the vibratory energy is inten-nittently interrupted to create a series of time-spaced bursts of vibratory oscillation and the frequency or amplitude of the vibration is modified during each of the bursts. This patent uses of bursts of **ultrasonic (^)** energy to reduce surface roughness of machined metal parts and to machine irregular contours into metal pieces.

United States Patent 3,673,475 to Britton has a drive circuit for generating pulses that are applied to a dental impact tool with a reciprocating armature. This patent discloses a drive circuit to generate pulses to 'pull-back' and then 'drive' an armature, a technique that is not applicable to **ultrasonic (^)** frequency vibratable tools.

None of the aforementioned patents teaches the use of profiled pulses of **ultrasonic (^)** frequency vibratory energy for a surgical effect on tissues of a patient, none addresses using profiled pulses of **ultrasonic (^)** frequency vibratory energy to suppress or eliminate the phenomenon described herein as mode coupling, and none suggests using profiled pulses of **ultrasonic (^)** frequency vibratory energy to minimize internal heating in the **ultrasonic (^)** applicator and the **ultrasonic (^)** motor. The patents do not disclose any benefits due to relationships between the magnitude of the pulses of **ultrasonic (^)** frequency vibratory energy and the duration of the pulses of **ultrasonic (^)** frequency vibratory energy.

United States Patent Number 4,827,911 to Broadwin has an **ultrasonic (^)** surgical handpiece with a switching means for automatically and repeatedly switching the amplitude of **ultrasonic (^)** vibration between a constant working high amplitude and a constant standby low amplitude, both used in combination with aspiration and irrigation, for enhanced fragmentation and improved surgical control. The invention works by interrupting continuous vibratory operation with on-off duty cycles, with suitable on-times for first, second, third, and fourth modes given as 50 milliseconds, milliseconds, 150 milliseconds, and 200 milliseconds, respectively. The continuous vibratory operation is interrupted with a repetition rate of at least 30 Hz so that the operator does not distractedly sense the operation at low amplitude.

The Broadwin patent does not address or appreciate using profiled pulses of **ultrasonic (^)** frequency vibratory energy to suppress or eliminate the phenomenon described herein as mode coupling, it does not address using profiled pulses of **ultrasonic (^)** frequency vibratory energy to reduce heating in the **ultrasonic (^)** applicator and the **ultrasonic (^)** motor, nor does it disclose any benefits due to relationships between the magnitude of the pulses of **ultrasonic (^)** frequency vibratory energy and the duration of the pulses of **ultrasonic (^)** frequency vibratory energy.

OBJECTS OF THE INVENTION It is, among other desirable attributes, an overall object of the present invention to provide a method and apparatus for delivering profiled pulses of **ultrasonic (^)** frequency vibratory energy to an **ultrasonic (^)** applicator for application to tissues of a patient with specific durations and magnitudes so that the **ultrasonic (^)** applicator can be driven to vibratory amplitudes previously not achievable, and for a more expedient surgical effect to be obtained.

It is a further object of the present invention to provide a method and apparatus for delivering profiled pulses of **ultrasonic (^)** frequency vibratory energy to an **ultrasonic (^)** applicator for application to tissues of a patient with specific durations and magnitudes so that the phenomenon described herein as mode coupling is reduced., minimized, suppressed, or eliminated.

It is a still further object of the present invention to provide a method and apparatus for delivering profiled pulses of **ultrasonic (^)** frequency vibratory energy to an **ultrasonic (^)** applicator for application to tissues of a patient with specific durations and magnitudes so that a more expedient surgical effect is obtained, and therefore, the effective dose of **ultrasonic (^)** frequency vibratory energy applied to the

tissues of a patient is minimized.

It is yet still a further object of the present invention to provide a method and apparatus for delivering profiled pulses of **ultrasonic (^)** frequency vibratory energy to an **ultrasonic (^)** applicator for application to tissues of a patient with specific durations and magnitudes so that the electrical power consumed by the **ultrasonic (^)** motor is minimized, resulting is a cooler running **ultrasonic (^)** motor.

It is a final object of the present invention to provide a method and apparatus for delivering profiled pulses of **ultrasonic (^)** frequency vibratory energy to an **ultrasonic (^)** applicator for application to tissues of a patient with specific durations and magnitudes so that internal heating of the **ultrasonic (^)** applicator is minimized.

SUMMARY OF THE INVENTION

The apparatus and method disclosed herein are directed toward achieving the aforementioned objects of the present invention. It has been learned through experimentation that previous switching between a constant high vibratory amplitude and a constant low vibratory amplitude results in mode coupling and the stimulation of parasitic modes of vibration, fundamentally limiting the efficient perfon-nance of those systems. It has been discovered that if a first time portion of a pulse **ultrasonic (^)** frequency vibratory energy is preferably profiled as described herein and kept below an upper limit of about fifty milliseconds, and a second time portion of the pulse of **ultrasonic (^)** frequency vibratory energy that follows the first time portion that is at least 3 times the time duration of the first time portion while the maximum vibratory amplitude is at least twice but not more than twenty times the minimum vibratory amplitude, then the mode coupling phenomenon can be suppressed or eliminated, thus allowing for operation at vibratory amplitudes previously not achievable. Thus, it is not how long the **ultrasonic (^)** frequency vibratory energy is delivered, but the combination of the magnitude of the pulse of **ultrasonic (^)** frequency vibratory energy and the duration and shape of the pulse of **ultrasonic (^)** frequency vibratory energy that eliminates mode coupling, expedites a surgical procedure, minimizes the effective dose of **ultrasonic (^)** energy to a patient, and minimizes heat generation in the **ultrasonic (^)** motor and the **ultrasonic (^)** applicator.

While the exact reason for successful operation with profiled pulses of **ultrasonic (^)** frequency vibratory energy is not completely understood, the results obtained unequivocally demonstrate the objects of this invention. It is believed, in.particular, that mode coupling is suppressed using this technique because there is insufficient time at the highest vibratory amplitudes to initiate vibration in and couple vibratory energy to parasitic modes of vibration. Further, it is believed that the previously unobtainable maximum vibratory amplitudes more efficiently and more effectively generate a surgical effect in the tissues of a patient, thus minimizing the effective dose of **ultrasonic (^)** frequency vibratory energy required to complete a surgical procedure. If the first time portion of the pulse of **ultrasonic (^)** frequency vibratory energy is less than about one millisecond mode coupling is suppressed but very little surgical effect is obtained. Therefore, in general, as the first time portion of the pulse of **ultrasonic (^)** frequency vibratory energy is shortened, an increased maximum magnitude of vibration is required to achieve and maintain an expedient surgical effect. The repetitive duty- cycle systems of prior patents failed to appreciate or recognize the relationship between the magnitude and duration of pulses of **ultrasonic (^)** frequency vibratory energy to achieve and maintain an effective and expedient surgical effect while eliminating problems due to mode coupling.

In general an **ultrasonic (^)** surgical apparatus for delivery of profiled pulses **ultrasonic (^)** frequency vibratory energy includes a housing to be held and manipulated by a user, an **ultrasonic (^)** motor supported within the housing, and an **ultrasonic (^)** applicator connected to the **ultrasonic (^)** motor and extending beyond the housing. Piezoelectric ceramics such as PZT-4 or PZT-8 are the preferred materials for the **ultrasonic (^)** motor. The **ultrasonic (^)** applicator may be of any shape, including, but not limited

to, an elongate solid probe, and elongate hollow probe, a flat radiating plate, or a convex radiating lens. The **ultrasonic (^)** applicator has a distal surface for engagement with tissues of a patient. The distal surface may, in the preferred embodiment, be shaped to achieve a desired surgical effect, including cutting, fragmentation, boring, and coagulation. The combination of the **ultrasonic (^)** motor and the **ultrasonic (^)** applicator are vibratable at a resonant frequency.

A power control circuit is electrically connected to the **ultrasonic (^)** motor for supplying electrical power to the **ultrasonic (^)** motor to produce **ultrasonic (^)** frequency vibratory energy that is applied to the **ultrasonic (^)** applicator to produce vibratory motion in the **ultrasonic (^)** applicator.

A vibration monitor circuit is electrically connected to the power control circuit for measuring an electrical vibration signal at the resonant frequency and proportional to a vibratory amplitude of the **ultrasonic (^)** applicator so that the power control circuit supplies electrical power to the **ultrasonic (^)** motor at the resonant frequency. The electrical vibration signal may be proportional to a current or a voltage of the electrical power supplied to the **ultrasonic (^)** motor by the power control circuit or it may be generated by a vibration sensing transducer located in or near the **ultrasonic (^)** motor.

A profile generator circuit is electrically connected to the power control circuit for producing a profiled pulse signal with a first profile and a maximum magnitude during a first time portion and a second profile and a minimum magnitude during a second time portion. The first time portion is generally the rising portion plus the time at maximum magnitude of the profiled pulse signal and the second time portion is generally the falling portion plus the time at minimum magnitude of the profiled pulse signal. The first profile is the shape of the leading edge of the profiled pulse signal as it ascends from the minimum magnitude to the maximum magnitude. The second profile is the shape of the trailing edge of the profiled pulse signal as it descends from the maximum magnitude to the minimum magnitude. The profiled pulse signal, in combination with the electrical vibration signal, is used in the power control circuit to adjust the supply of electrical power to the **ultrasonic (^)** motor to produce profiled pulses of **ultrasonic (^)** frequency vibratory energy.

To best suppress the phenomenon described herein as mode coupling and to achieve maximum vibratory performance the first time portion should be less than fifty milliseconds in duration, but not less than one millisecond in duration to ensure a sufficient surgical effect. The preferred range for the first time portion is between about five milliseconds and about forty milliseconds. The second time portion should be greater than three times the duration of the first time portion. The preferred duration for the second time portion is between about four and ten times the duration of the first time portion. The maximum magnitude should be in the range between two and twenty times the minimum magnitude to achieve an expedient surgical effect. The preferred range for the maximum magnitude is between four and ten times the minimum magnitude.

It is prefer-red that the rising portion of the first profile and the falling portion of the second profile be monotonically increasing and decreasing shapes, respectively. Monotonically, increasing refers to a shape with a continuous rise with time, without downward dips. Monotonically decreasing refers to a shape with a continuous fall with time, without upward bumps.

The preferred range of resonant frequencies for **ultrasonic (^)** surgical devices with **ultrasonic (^)** applicators shaped like elongate probes, either solid or hollow, is between 20 kHz and 80 kHz.

The preferred range of resonant frequencies for **ultrasonic (^)** surgical devices with **ultrasonic (^)** applicators shaped like a flat radiating plate or a convex radiating lens is between 80 kHz and 200 kHz.

A profiled pulse signal may be generated in any time sequence such that the constraints expressed above

are met. However, it has been found that mode coupling is best suppressed if a profiled pulse signal is generated not more than twenty times per second. To minimize the effective dose of **ultrasonic (^)** vibratory energy applied to the tissues of a patient it is preferred that the profiled pulse signal be generated even less often, for example ten times per second.

The second time portion of the profiled pulse signal may vary between consecutive profiled pulse signals. This has the effect of further reducing mode coupling and the stimulation of parasitic modes of vibration.

The preferred **ultrasonic (^)** surgical apparatus may have an axis passing through the **ultrasonic (^)** motor and the **ultrasonic (^)** applicator. The **ultrasonic (^)** motor and the **ultrasonic (^)** applicator are symmetric about the axis along which they are disposed for delivery of **ultrasonic (^)** frequency vibratory energy in the direction of the axis.

A method of using profiled pulses of **ultrasonic (^)** frequency vibratory energy to generate an expedient surgical effect and suppress or eliminate mode coupling is disclosed. The method includes the steps of engaging a medium, such as tissues of a patient, with the **ultrasonic (^)** applicator of the **ultrasonic (^)** surgical apparatus, and powering the **ultrasonic (^)** surgical apparatus with profiled pulses of **ultrasonic (^)** frequency vibratory energy, the profiled pulses with a first profile and a maximum magnitude during a first time portion and a second profile and a minimum magnitude during a second time portion, the second time portion greater than three times the duration of the first time portion, the maximum magnitude between two and twenty times the minimum magnitude, and the first time portion between one millisecond and fifty milliseconds in duration.

BRIEF DESCRIPTION OF THE DRAWINGS

The novel features of the invention are set forth in the appended claims. The invention will be best understood by reference to the following figures when read in conjunction with the detailed description of the invention.

Fig. I is a functional block diagram and partial circuit diagram of an **ultrasonic (^)** surgical apparatus and circuits for delivery of profiled pulses of **ultrasonic (^)** frequency vibratory energy.

Fig. 2 is a waveform diagram illustrating the components of the profiled pulse signal and profiled pulses of **ultrasonic (^)** frequency vibratory energy.

Fig. 3 shows the form of four types of **ultrasonic (^)** applicators.

DETAILED DESCRIPTION OF THE INVENTION

Referring to the drawings, Figure 1 is a functional block diagram and partial circuit diagram of an **ultrasonic (^)** surgical apparatus 10 and circuits 30 for delivery of profiled pulses of **ultrasonic (^)** frequency vibratory energy. The **ultrasonic (^)** surgical apparatus 10 includes a housing I I to be held and manipulated by a user, an **ultrasonic (^)** motor 12 supported within the housing 11, and an **ultrasonic (^)** applicator 13 connected to the **ultrasonic (^)** motor 12 and extending beyond the housing 11.

In Figure 1 the **ultrasonic (^)** applicator 13 depicted is an elongate probe. The housing 11 may be fabricated from metals or plastics, the preferred materials are steam sterilizable plastics such as Delrin (acetal homopolymer) or Radel (polyphenylsulphone). The **ultrasonic (^)** motor 12 may be constructed from piezoelectric ceramics or magnetostrictive metals. The preferred materials are piezoelectric ceramics such as PZT-4 or PZT-8. The **ultrasonic (^)** applicator 13 may be fabricated from metal materials such as aluminum., stainless steel, or titanium. The preferred materials for the **ultrasonic (^)** applicator 13 are

titanium or titanium alloys such as Ti6Al4V. In combination, the **ultrasonic (^)** motor 12 and the **ultrasonic (^)** applicator 13 have a resonant frequency. The resonant frequency is the frequency of preferred longitudinal vibration. The **ultrasonic (^)** applicator 13 has a distal surface 14 for engagement with tissues of a patient. The distal surface 14 may be shaped to achieve a desired surgical effect. The **ultrasonic (^)** motor 12 and the **ultrasonic (^)** applicator 13 may be disposed along and are symmetric about an axis 15.

A power control circuit 16 is electrically connected to the **ultrasonic (^)** motor 12 for supplying electrical power to the **ultrasonic (^)** motor 12 to produce **ultrasonic (^)** frequency vibratory energy that is applied to the **ultrasonic (^)** applicator 13 to produce vibratory motion in the **ultrasonic (^)** applicator 13.

An automatic gain control element 36 receives an electrical vibration signal from a vibratory monitor circuit 17 and a profiled pulse signal from a profile generator circuit 18. The automatic gain control element 36 adjusts the input to a power amplifier 37 so that electrical power is supplied to the **ultrasonic (^)** motor 12 through an output transformer 38 at the resonant frequency to produce profiled pulses of **ultrasonic (^)** frequency vibratory energy. A preferred embodiment of the circuit elements of the automatic gain control element 36 is shown in the application notes for the Analog Devices 633, an integrated circuit multiplier, 1992 Analog Devices Special Linear Reference Manual, pages 2-52,53. In an alternative embodiment, the automatic gain control element 36 may be replaced with an automatic phase control element that includes a phase- locked-loop circuit that maintains a selected phase relationship between the electrical vibration signal and a reference signal.

The vibration monitor circuit 17 is electrically connected to the power control circuit 16 for measuring an electrical vibration signal at the resonant frequency and proportional to a vibratory amplitude of the **ultrasonic (^)** applicator 13. The preferred electrical vibration signal is proportional to a current of the electrical power supplied by the power control circuit 16. A current sense resistor 31 may be located in-line with the primary of the output transformer 38. The voltage across the current sense resistor 31 is applied to and amplified by a signal amplifier 32 and the output of the signal amplifier 32 is applied to a **band-pass filter (^)** 33. The output of the **band-pass filter (^)** 33 is the electrical vibration signal that is in electrical communication with the power control circuit 16.

The profile generator circuit 18 is electrically connected to the power control circuit 16 for producing a profiled pulse signal. A digital pulse generator 34 generates a pulse signal that is applied to a low-pass filter 35. The low-pass filter 35 profiles the leading and trailing edges of the pulse signal generated by the digital pulse generator 34. The output of the low-pass filter 35 is the profiled pulse signal that is in electrical communication with the power control circuit 16.

A detailed waveforin diagram illustrating the components of the profiled pulse signal and profiled pulses of **ultrasonic (^)** frequency vibratory energy is shown in Figure 2. Figure 2a shows the output of the digital pulse generator 34, with a maximum magnitude 20 during a first time portion 21 and a minimum magnitude 22 during a second time portion 23. To best suppress mode coupling the first time portion 21 should be in the range between one millisecond and fifty milliseconds, and the second time portion 23 should be greater than three times the duration of the first time portion 21.

The preferred duration for the first time portion 21 is between five milliseconds and forty milliseconds. For example, if the first time portion 21 is ten milliseconds then the second time portion 23 must be greater than thirty milliseconds in duration, preferably greater than forty milliseconds. The maximum magnitude 20 should be in the range between two and twenty times the minimum magnitude 22. The preferred range for the maximum magnitude is between four and ten times the minimum magnitude 22. For example, if the minimum magnitude 22 has a value of two then the maximum magnitude must be between four and forty, preferably between eight and twenty.

Figure 2b shows the profiled pulse signal, a result of the application of the output of the digital pulse generator 34 to the low-pass filter 35. The profiled pulse signal has a monotonically increasing shape 24 and a maximum magnitude 20 and a monotonically decreasing shape 25 and a minimum magnitude 22.

Figure 2c shows profiled pulses of **ultrasonic (^)** frequency vibratory energy that correspond to application of the profiled pulse signal, in combination with the electrical vibration signal, to the power control circuit 16.

The profiled pulse signal may be generated as a single event or it may be repeated. To best suppress mode coupling and minimize heating in the **ultrasonic (^)** motor and the **ultrasonic (^)** applicator the repetition rate should be less than twenty times per second. The preferred repetition rate is in the range between four and ten times per second.

Figure 3 shows four examples of **ultrasonic (^)** applicators. The **ultrasonic (^)** applicator may be an elongate solid probe as shown in Figure 3a, an elongate hollow probe as shown in Figure 3b, a flat radiating plate as shown in Figure 3c, or a convex radiating lens as shown in Figure 3d.

Ultrasonic (^) surgical devices typically operate at frequencies between 20 kHz and 80 kHz, most specifically when the **ultrasonic (^)** applicator is shaped like an elongate solid or hollow probe.

When the **ultrasonic (^)** applicator is shaped like a flat radiating plate or a convex radiating lens the operating frequency may be higher, from 80 kHz up to about 200 kHz.

Claims

CLAIMS

What is claimed is 1. An **ultrasonic (^)** surgical apparatus for delivery of profiled pulses of **ultrasonic (^)** frequency vibratory energy, the **ultrasonic (^)** surgical apparatus with a housing to be held and manipulated by a user, an **ultrasonic (^)** motor supported within the housing, an **ultrasonic (^)** applicator connected to the **ultrasonic (^)** motor and extending beyond the housing, the **ultrasonic (^)** applicator with a distal surface for engagement with tissues of a patient and, in combination with the **ultrasonic (^)** motor, vibratable at a resonant frequency, and the improvement comprising:

a power control circuit electrically connected to the **ultrasonic (^)** motor for supplying electrical power to the **ultrasonic (^)** motor to produce **ultrasonic (^)** frequency vibratory energy that is applied to the **ultrasonic (^)** applicator; a vibration monitor circuit electrically connected to the power control circuit for measuring an electrical vibration signal at the resonant frequency and proportional to a vibratory amplitude of the **ultrasonic (^)** applicator so that the power control circuit supplies electrical power to the **ultrasonic (^)** motor at the resonant frequency; and a profile generator circuit electrically connected to the power control circuit for producing a profiled pulse signal, the profiled pulse signal with a first profile and a maximum magnitude during a first time portion and a second profile and a minimum magnitude during a second time portion, the second time portion greater than three times the duration of the first time portion, the first time portion between one millisecond and fifty milliseconds in duration, and the maximum magnitude in the range between two and twenty times the minimum magnitude, so that, in combination with the electrical vibration signal, the power control circuit adjusts the supply of electrical power to the **ultrasonic (^)** motor to produce profiled pulses of **ultrasonic (^)** frequency vibratory energy.

2. The **ultrasonic (^)** surgical apparatus of claim I wherein the resonant frequency is between 20 kHz and 200 kHz.

3. The **ultrasonic (^)** surgical apparatus of claim 1 wherein a profiled pulse signal is generated not more than twenty times per second.

4. The **ultrasonic (^)** surgical apparatus of claim I wherein the second time portion varies between consecutive profiled pulse signals.

5. The **ultrasonic (^)** surgical apparatus of claim I wherein the **ultrasonic (^)** applicator is an elongate solid probe.

6. The **ultrasonic (^)** surgical apparatus of claim I wherein the **ultrasonic (^)** applicator is an elongate hollow probe.

7. The **ultrasonic (^)** surgical apparatus of claim I wherein the **ultrasonic (^)** applicator is a flat radiating plate so that the **ultrasonic (^)** frequency vibratory energy is distributed over the distal surface of the **ultrasonic (^)** applicator.

8. The **ultrasonic (^)** surgical apparatus of claim I wherein the **ultrasonic (^)** applicator is a convex radiating lens so that the **ultrasonic (^)** frequency vibratory energy is distributed over the distal surface of the **ultrasonic (^)** applicator and can be concentrated at a depth in the tissues of a patient.

9. The **ultrasonic (^)** surgical apparatus of claim I wherein the first profile has a monotonically increasing shape.

10. The **ultrasonic (^)** surgical apparatus of claim I wherein the second profile has a monotonically decreasing shape.

11. The **ultrasonic (^)** surgical apparatus of claim I wherein the first profile is a combination of a monotonically increasing shape and the maximum magnitude.

12. The **ultrasonic (^)** surgical apparatus of claim I wherein the second profile is a combination of a monotonically decreasing shape and the minimum magnitude.

13. The **ultrasonic (^)** surgical apparatus of claim I wherein the **ultrasonic (^)** motor and the **ultrasonic (^)** applicator are symmetric about an axis along which they are disposed for delivery of **ultrasonic (^)** frequency vibratory energy in the direction of the axis.

14. The **ultrasonic (^)** surgical apparatus of claim 1 wherein the electrical vibration signal is generated by a vibration sensing transducer located in or near the **ultrasonic (^)** motor.

15. The **ultrasonic (^)** surgical apparatus of claim I wherein the electrical vibration signal is proportional to a current of the electrical power supplied to the **ultrasonic (^)** motor by the power control circuit.

16. The **ultrasonic (^)** surgical apparatus of claim 1 wherein the electrical signal is proportional to a voltage of the electrical power supplied to the **ultrasonic (^)** motor by the power control circuit.

17. A method of using profiled pulses of **ultrasonic (^)** frequency vibratory energy to generate an expedient surgical effect and suppress or eliminate mode coupling, the method including the steps o f:

engaging the tissues of a patient with an **ultrasonic (^)** applicator of an **ultrasonic (^)** surgical apparatus, and powering the **ultrasonic (^)** surgical apparatus with profiled pulses of **ultrasonic (^)** frequency

vibratory energy, the profiled pulses with a first profile and a maximum magnitude during a first time portion and a second profile and a minimum magnitude during a second time portion, the second time portion greater than three times the duration of the first time portion, the maximum magnitude between two and twenty times the minimum magnitude, and the first time portion between one millisecond and fifty milliseconds in duration.

18. An **ultrasonic (^)** surgical apparatus for delivery of profiled pulses of **ultrasonic (^)** frequency vibratory energy, the **ultrasonic (^)** surgical apparatus with a housing to be held and manipulated by a user, an **ultrasonic (^)** motor supported within the housing, an **ultrasonic (^)** applicator connected to the **ultrasonic (^)** motor and extending beyond the housing, the **ultrasonic (^)** applicator with a distal surface for engagement with tissues of a patient and, in combination with the **ultrasonic (^)** motor, vibratable at a resonant frequency, and the improvement comprising:

a power control circuit electrically connected to the **ultrasonic (^)** motor for supplying electrical power to the **ultrasonic (^)** motor to produce **ultrasonic (^)** frequency vibratory energy that is applied to the **ultrasonic (^)** applicator; a vibration monitor circuit electrically connected to the power control circuit for measuring an electrical vibration signal at the resonant frequency and proportional to a vibratory amplitude of the **ultrasonic (^)** applicator so that the power control circuit supplies electrical power to the **ultrasonic (^)** motor at the resonant frequency; a profile generator circuit electrically connected to the power control circuit for producing a profiled pulse signal, the profiled pulse signal with a first profile and a maximum magnitude during a first time portion and a second profile and a minimum magnitude during a second time portion, so that. in combination with the electrical vibration signal, the power control circuit adjusts the supply of electrical power to the **ultrasonic (^)** motor to produce profiled pulses of **ultrasonic (^)** frequency vibratory energy; the second time portion greater than three times the duration of the first time portion; the first time portion between one millisecond and fifty milliseconds in duration; the maximum magnitude in the range between two and twenty times the minimum magnitude; and the profiled pulse signal generated not more than twenty times per second.

19. The **ultrasonic (^)** surgical apparatus of claim 18 wherein the resonant frequency is between 20 kHz and 200 kHz.

20. The **ultrasonic (^)** surgical apparatus of claim 18 wherein the second time portion varies between consecutive profiled pulse signals.

21. A method for surgically affecting tissue in an animal by applying **ultrasonic (^)** frequency vibratory energy comprising:

applying a first profile of a pulse of **ultrasonic (^)** frequency vibratory energy said first profile having a maximum amplitude during a first time portion; applying a second profile of a pulse of **ultrasonic (^)** frequency vibratory energy said second profile having a minimum amplitude during a second time portion wherein; the second time portion is between one millisecond and fifty milliseconds in duration; the second time portion is at least three times greater than the first time portion; ând the maximum amplitude is in the range between two to twenty items the minimum amplitude; and repeating the application of said first and second profiles of a pulse of **ultrasonic (^)** frequency vibratory energy.

22. The method of Claim 21 wherein said second time portion is between four and ten times the duration of the first time portion.

23. The method of Claim 21 wherein the first profile is monotonically increasing and the second profile is monotonically decreasing.

24. The method of Claim 21 wherein said pulse has a shape substantially as shown in Figure 2c.

25. The method of Claim 21 wherein said pulse is generated no more than twenty times per second.

26. The method of Claim 25 wherein said pulse is generated no more than ten times per second.

27. A method for providing profiled pulses of **ultrasonic (^)** frequency vibratory energy to an **ultrasonic (^)** motor of an **ultrasonic (^)** surgical applicator said method comprising generating a profiled pulse signal having substantially the shape depicted in Figure 2b using a profile generator circuit that is electrically connected to a power control circuit said power control circuit in electrical connection with said motor.